From: Jefferson, Erica
Date: April 9, 2013 21:20:22 EDT
To: Rob Garver **Cc:** Mark Schoofs
Subject: Re: Follow up on fact check

Here's what they sent back re MDS:We did not receive evidence suggesting that the original bioequivalence studies were flawed, as most if not all of the confirmatory audit, reassay, or repeat studies supported the original conclusions of bioequivalence.

From: Rob Garver
Sent: Tuesday, April 09, 2013 08:44 PM
To: Jefferson, Erica **Cc**: Mark Schoofs, Seife
Subject: **Re: Follow up on fact check**

Erica,

Thanks for this.

So you are aware, we are holding the story until Thursday, so we have time to consider your responses.

Your email cuts off at #24. Did you have responses to any of the remaining facts/quotes that I sent yesterday? Or to the MDS material I sent you?
Please advise.

Rob Garver
Contributor
ProPublica

On Apr 9, 2013, at 8:36 PM, "Jefferson, Erica" wrote:

Cetero Facts/Quotes 04/09/13
1) Approximately 100 drugs, including a generic form of ibuprofen, a chemotherapy compound, and an addictive painkiller were approved for market in the US based at least in part on testing done at Cetero during the time in question.
2) 81 of these drugs were generic versions of brand-name products; the remainder were new drugs

3) The FDA has twice set six-month deadlines for companies to redo, reanalyze, or reaudit tests done by Cetero. In both cases, a large number of companies failed to meet the deadline.Response:The FDA has twice set six-month deadlines for companies to redo, reanalyze, or reaudit tests done by Cetero. Most of the companies met the deadline; a few have not yet submitted new studies. In addition some of the firms have made decisions to discontinue marketing of their drug products rather than repeating or auditing the studies.
4) As of today, the FDA has received the required data for 51 of the suspect drugs and has completed its internal review of 30 of those. The agency has not released either the data from the 51 submissions or its 30 reviews.Response: As of today, the FDA has received the required data for 53 of the suspect generic drugs drugs and has completed its internal review of 21 of those. The agency has not released either the data from the 53 submissions or its 21 reviews.
5) The agency refuses to release the names of the drugs being reassessed because doing so would reveal “confidential commercial information”Response: This information is protected by law from disclosure.
6) The FDA notes that to this point it has found no discrepancy between the drugs retested and the original results produced by Cetero.
7) Woodcock quote: “It is non-trivial to have to redo all this, to withdraw drugs, to alarm the public and the providers for a large range of drugs. There are consequences. To repeat the studies requires human experimentation, and that is not totally without risk.”
8) Woodcock said the FDA’s risk assessment found the potential for harm from drugs tested by Cetero to be “quite low.””
9) The FDA described the assessment as “fluid” and “ongoing."
10) Quote from former FDA head David Kessler: “If there are problems with the scientific studies, as there have been in this case, then the FDA’s review of those problems needs to be transparent.”Response: We've been as transparent as possible given the legal protections surrounding an FDA investigation of this or any type. The issue is not a lack of transparency but rather the difficulty of explaining why the problems we identified at Cetero, which on their face would appear to be highly significant in terms of patient risk, fortunately were not.
11) Kessler said that making the agency’s reviews public would let the medical community “understand the basis for the agency’s actions.”Response: We agree that furthering clinicians' understanding of problems that could put patients at risk is important and we try to make public as much data and analysis as we are permitted to disclose in our public communications and outreach to physicians. In this case, our early analysis--that the probability of risk was likely to be low--guided our public communications. Ultimately, our initial judgment and decisions have been validated by our investigation and the scientific findings produced to date. The process has been long because of the number of products involved and our wish to be thorough and accurate in both our requests for and our review of the data.

12) Kessler quote: “FDA may be right here, but if it wants public confidence, they should be transparent. Otherwise it's just a black box.”Response: See response to 11.
13) Quote from another former senior FDA official, who spoke on condition of anonymity: “They’re keeping it all in the dark. It’s not transparent at all.”
14) Woodcock quote in response to the point that the EMA withdrew seven drugs from the market: “Europe had a smaller handful of drugs, and they may not have engaged in as extensive negotiation and investigations with the company as we did.”
15) Woodcock said the FDA would have disclosed more if the agency believed there was a risk to public health.
16) Woodcock quote: “We believe that this did not rise to the level where the public should be notified. We felt it would result in misunderstanding and inappropriate actions.”
17) Data from studies conducted during the period in question is cited in peer-reviewed medical journals.
18) An attorney who represented Cetero and later, PRACS Institute, called the FDA’s approach to the company “overkill” and said that it led to the bankruptcy of both companies and the ultimate loss of more than 1,000 jobs.
19) Quote from a former FDA inspector who criticized the agency for failing to take stronger action against the drugs on the market based on Cetero tests. “They could have done more. They should have done more.”
20) FDA says that it has found no increase in side effects or lack of efficacy among drugs tested by Cetero.
21) FDA required drug company Schering-Plough to test its proposed IV formulation of Temodar against its already-approved oral version. The “pivotal” test was performed at Cetero. In 2011, the FDA contacted Merck (which had acquired Schering-Plough) and informed the company of the problems at Cetero. The tests on Temodar fell in the timeframe during which the FDA ultimately required retests or reanalysis. However, a Merck spokesperson said the FDA has requested no additional analysis from the company.Response: As previously stated, we can’t answer any questions on Temodar due to confidentiality.
22) Woodcock said that in some cases, companies were able to provide alternative test results to the agency that satisfied the retesting requirement.
23) Woodcock said that the FDA did not require drug companies to remove Cetero data from labels because the agency’s overall recommendation had not changed.
24) Quote from a research physician who participated in the Temodar study and was “taken aback” to find out that the data was called into question: “I think we should have been told."Response: As previously stated, we can’t answer any questions on Temodar due to confidentiality.